

W. Scott Mitchell
Michael P. Manning
HOLLAND & HART LLP
401 North 31st Street
Suite 1500
Billings, MT 59101-1277
Telephone: (406) 252-2166
Fax: (406) 252-1669
smitchell@hollandhart.com
mpmanning@hollandhart.com

Counsel for Defendant

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

LESLIE "CASEY" and PAM
MARLENEE, each Individually,
and on behalf of M.M., their
minor child,

Plaintiffs,

V.

GLAXOSMITHKLINE LLC,
Defendant.

No. 1:15-cv-00026-SPW-CSO

**BRIEF IN SUPPORT OF
MOTION TO DISMISS FOR
LACK OF PERSONAL
JURISDICTION**

INTRODUCTION

This product liability action concerns Zofran®, a prescription medication manufactured by defendant GlaxoSmithKline LLC (“GSK”) and approved by the federal Food and Drug Administration for the treatment of nausea. Plaintiff Pam Marlenee alleges that she ingested Zofran® while pregnant and that her child, M.M., was subsequently born with congenital birth defects that Plaintiffs attribute to her use of Zofran®.

Plaintiffs cannot establish personal jurisdiction over GSK in Montana. First, Plaintiffs cannot demonstrate that GSK possesses the requisite “minimum contacts” with Montana to justify specific personal jurisdiction as a matter of constitutional due process. Plaintiffs have not (and cannot) allege facts demonstrating that any of GSK’s allegedly wrongful acts and omissions giving rise to these claims has any connection with Montana. GSK is part of a group of global pharmaceutical companies, and its U.S. headquarters are centralized in North Carolina with other significant operations in Pennsylvania. GSK has never manufactured Zofran® in Montana. GSK has never engaged in product development of Zofran® in Montana. GSK never tested

Zofran® in pre-clinical trials in Montana. GSK is not currently conducting any clinical trials or other testing of Zofran® in Montana. None of the Zofran® labeling that plaintiffs now contend was inadequate as part of their failure-to-warn product liability claims was created or approved in Montana. In sum, GSK lacks sufficient minimum contacts with Montana here to sustain specific jurisdiction in the State.

Second, GSK is not subject to general jurisdiction in Montana. Under recent Supreme Court precedent, a company is subject to general jurisdiction only in its place of incorporation and its principal place of business unless an “exceptional circumstance” renders it “at home” elsewhere. *See Daimler AG v. Bauman*, 134 S.Ct. 746, 753 (2014). As described below, GSK is not incorporated or headquartered in Montana, and this case does not present any exceptional circumstance obviating the rule established by the Supreme Court.

GSK is a limited liability company (“LLC”) organized under the laws of the State of Delaware whose sole member is GlaxoSmithKline Holdings (Americas) Inc. (“GSK Holdings”). GSK Holdings is a Delaware corporation with its headquarters and principal place of

business in Delaware. GSK's U.S. operations and corporate offices are located in North Carolina and Pennsylvania. Exercising general jurisdiction over GSK in Montana would violate due process under *Daimler*.

For these reasons, GSK's motion to dismiss should be granted.

BACKGROUND

The GlaxoSmithKline group of companies is a worldwide pharmaceutical and consumer healthcare business with more than 100,000 employees in 115 countries and manufacturing sites around the globe. *See* Declaration of Steve Sons, attached as Ex. A, at ¶¶ 10-12. GSK—a Delaware limited liability company whose sole member is a Delaware corporation with its principal place of business in Delaware—is the entity responsible for GlaxoSmithKline's U.S. pharmaceutical business. *Id.*, ¶¶ 2-3, 13; Compl. ¶ 19. By any measure, GSK's Montana operations comprise only a tiny portion of its nationwide total. *See id.*, ¶¶ 13, 18-20. This case, however, has nothing to do with GSK's Montana operations or contacts.

On April 3, 2015, the Marlenees filed suit alleging that M.M. was born with a cleft lip and cleft palate in 1998 as a result of her mother's

use of Zofran® while pregnant. *See, e.g.*, Compl., ¶¶ 81-90. In their Complaint, the Marlenees did not allege that Pam Marlenee was prescribed Zofran® in Montana or purchased the drug here. *See generally* Compl. Nor did they allege that any of GSK’s specific Zofran®-related conduct underlying their nine separate causes of action occurred in Montana. *See id.*

Instead, the Marlenees only alleged generally that GSK is subject to jurisdiction in Montana because it conducts a substantial amount of business in the State, has a resident agent here, and “engaged in interstate commerce when [it] advertised, promoted, supplied and sold pharmaceutical products, including Zofran to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public, deriving substantial revenue in [Montana].” *Id.*, ¶¶ 17, 21.

LEGAL STANDARD

In opposing a motion to dismiss for lack of personal jurisdiction, “the plaintiff bears the burden of establishing that jurisdiction is appropriate.” *Picot v. Weston*, 780 F.3d 1206, 1211 (9th Cir. 2015) (quoting reference omitted). Although uncontroverted allegations must

be taken as true, the plaintiff cannot “simply rest on the bare allegations of its complaint.” *Schwarzenegger v. Fred Martin Motor Co.*, 374 F.3d 797, 800 (9th Cir. 2004). When the motion is made on written materials rather than an evidentiary hearing, the plaintiff must make a prima facie showing of jurisdictional facts. *Id.* Although that standard requires the court to resolve factual disputes in the plaintiff’s favor, *id.*, it also requires the plaintiff “to come forward with facts, by affidavit or otherwise, supporting personal jurisdiction.” *Amba Marketing Sys., Inc. v. Jobar Int’l, Inc.*, 551 F.2d 784, 787 (9th Cir. 1977).

ARGUMENT

There are two categories of personal jurisdiction, both rooted in *International Shoe Co. v. Washington*, 326 U.S. 310 (1945). Specific jurisdiction—which “has become the centerpiece of modern jurisdiction theory”—tests the “relationship among the defendant, the forum, and the litigation.” *Daimler*, 134 S.Ct. at 755, 758 (quoting references omitted). For specific jurisdiction to exist, the suit must “arise out of or relate to the defendant’s contacts with the forum.” *Helicopteros Nacionales de Columbia, S.A. v. Hall*, 466 U.S. 408, 414 n.8 (1984). General jurisdiction, on the other hand, permits a State to exercise

jurisdiction over a defendant based on contacts unrelated to the underlying suit. *See Daimler*, 134 S.Ct. at 754. General jurisdiction exists only when the defendant’s “affiliations with the State are so continuous and systematic as to render [it] essentially at home in the forum State.” *Id.* (quoting *Goodyear Dunlop Tires Ops., S.A. v. Brown*, 131 S.Ct. 2846, 2851 (2011) (internal quotation marks omitted)).

GSK is not subject to personal jurisdiction in Montana under either theory. The Marlenees’ claims do not stem from any of GSK’s Montana-based activities—and the Marlenees have not alleged that they do—and GSK’s contacts with Montana do not render it at home here.

I. GSK Is Not Subject to Specific Jurisdiction in Montana in this Case.

The Ninth Circuit employs a three-part test to determine whether a defendant is subject to specific jurisdiction in a particular State:

(1) The non-resident defendant must purposefully direct his activities or consummate some transaction with the forum or resident thereof; or perform some act by which he purposefully avails himself of the privilege of conducting activities in the forum, thereby invoking the benefits and protections of its laws;

(2) the claim must be one which arises out of or relates to the defendant's forum-related activities; and

(3) the exercise of jurisdiction must comport with fair play and substantial justice, *i.e.*, it must be reasonable.

Picot, 780 F.3d at 1211.

The precise nature of the inquiry, however, depends on the nature of the claim at issue. *Id.* at 1212. For tort claims, the court applies the “purposeful direction” test. *Id.* Under that test—which itself has three parts—a defendant purposefully has directed its activities at the forum if it (1) committed an intentional act; (2) expressly aimed at the forum State; (3) causing harm that the defendant knew was likely to be suffered in the forum State. *Id.* at 1214 (quoting *Schwarzenegger*, 374 F.3d at 803).

The “purposeful direction” test is constrained by the limits on a State's adjudicative authority, which “principally protect the liberty of the nonresident defendant—not the convenience of plaintiffs or third parties.” *See Walden*, 134 S.Ct. at 1122; *Picot*, 780 F.3d at 1214. Thus, only contacts that the defendant *itself* creates with the forum State are relevant for determining whether specific jurisdiction exists. *Walden*, 134 S.Ct. at 1122. Jurisdiction cannot be established “by demonstrating

contacts between the plaintiff (or third parties) and the forum State,” no matter how significant the plaintiff’s (or third parties’) contacts might be. *Id.* Similarly, the analysis “looks to the defendant’s contacts with the State itself, not the defendant’s contacts with persons who reside there.” *Id.* By itself, “mere injury to a forum resident is not a sufficient connection to the forum” to establish specific jurisdiction. *Picot*, 780 F.3d at 1214 (quoting *Walden*, 134 S.Ct. at 1125).

Here, the Marlenees have not come close to making a prima facie showing that their claims arise out of any GSK activity in Montana. *See id.* at 1211 (plaintiff has the burden of proving the first two prongs of the specific jurisdiction test). Indeed, they have not even *alleged* facts that arguably would give rise to specific jurisdiction.

Plaintiffs have not alleged that GSK researched, manufactured, tested, or labeled in Montana the Zofran® that Pam Marlenee was prescribed, nor can plaintiffs do so, since those activities all took place in other States. *See* Ex. A, ¶¶ 14-19. Nor did they allege that Pam Marlenee was prescribed Zofran® in Montana or purchased her Zofran® in Montana. The absence of such allegations alone is dispositive. Without even alleging that their claims arise out of some

action that GSK directed at Montana, the Marlenees cannot contend that GSK is subject to specific personal jurisdiction here.

The Marlenees' boilerplate allegation that GSK "has committed a tort, in whole or in part, in this judicial district," *see* Compl., ¶ 17, does not change the analysis. Absent supporting facts, such conclusory, formulaic recitations do not overcome the rule that a plaintiff cannot "simply rest on the bare allegations of its complaint" to establish personal jurisdiction. *See MGA Entm't, Inc. v. Innovation First, Inc.*, 525 F. App'x 576, 578 (9th Cir. 2013) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Likewise, it is irrelevant that the Marlenees currently live in Montana. *See* Compl., ¶ 18; *Walden*, 134 S.Ct. at 1122 ("[T]he Plaintiff cannot be the only link between the defendant and the forum.").¹

In short, the Marlenees have not alleged that their claims arise out of any contacts that GSK may have with Montana. Nor can they.

¹ In fact, even if GSK *knew* that the Marlenees had strong Montana connections (setting aside whether plaintiffs, in fact, do have such connections), that knowledge still would not subject GSK to specific personal jurisdiction here, given that the Marlenees' claims are based on alleged acts or omissions that occurred in other States. *Walden*, 134 S.Ct. at 1124 (considering a defendant's knowledge of a plaintiff's "strong forum connections" would "impermissibly allow[] a plaintiff's contacts with the defendant and forum to drive the jurisdictional analysis").

GSK is a global pharmaceutical company whose U.S. headquarters are centralized in North Carolina with other significant operations in Pennsylvania. Ex. A, ¶4, 20. GSK has never manufactured Zofran® in Montana. *Id.*, ¶14. GSK has never engaged in product development of Zofran® in Montana. *Id.* GSK never tested Zofran® in pre-clinical trials in Montana. *Id.* GSK is not currently conducting any clinical trials or other testing of Zofran® in Montana. *Id.*, ¶¶14, 16. None of the allegedly inadequate labeling for Zofran® that plaintiffs are likely to challenge through their failure-to-warn product liability claims was created, approved, or otherwise managed in Montana. *Id.*, ¶14. No company-wide decision-making regarding the marketing and promotion of Zofran® occurred in Montana. *Id.*, ¶15.

Given the remoteness of GSK's allegedly wrongful conduct from Montana, plaintiffs cannot demonstrate sufficient minimum contacts between GSK and Montana to justify an exercise of specific jurisdiction over GSK in this case. Any exercise of specific jurisdiction would violate due process.

II. GSK Is Not Subject to General Jurisdiction in Montana.

A. *Daimler* Clarified that General Jurisdiction is Very Narrow.

The Ninth Circuit has long recognized that “courts have been understandably reluctant to exercise general jurisdiction.” *Tuazon v. R.J. Reynolds Tobacco Co.*, 433 F.3d 1163, 1172 (9th Cir. 2006). Yet, like nearly every other court in the country, courts in this circuit traditionally applied a test that permitted the exercise of general jurisdiction over a corporation engaging in “substantial and continuous” business in a State, even if the company’s contacts did not rise to the level of a “home away from home.” *See id.* at 1172-75.

In *Daimler AG v. Bauman*, 134 S.Ct. 746, 753 (2014), the Supreme Court fundamentally recast and narrowed that view of general jurisdiction. The Court clarified that *International Shoe* had used the words “continuous and systematic” only to “describe instances in which the exercise of *specific* jurisdiction would be appropriate.” 134 S.Ct. at 761 (emphasis in original). And it rejected as “unacceptably grasping” any formulation that would “approve the exercise of general jurisdiction in every State in which a corporation engages in a substantial,

continuous, and systematic course of business.” *Id.* (internal quotation marks omitted). Accordingly, for purposes of assessing general jurisdiction, “the inquiry . . . is not whether a foreign corporation’s in-forum contacts can be said to be in some sense ‘continuous and systematic,’ it is whether that corporation’s affiliations with the State are so ‘continuous and systematic’ ***as to render [it] essentially at home in the forum State.***” *Id.* (quoting *Goodyear*, 131 S.Ct. at 2851) (emphasis added).

The Court explained what it means to be “at home” in a forum. First, it explained that the general jurisdiction inquiry does not “focu[s] solely on the magnitude of the defendant’s in-state contacts.” 131 S.Ct. at 762 n.20. Rather, the test “calls for an appraisal of a corporation’s activities in their entirety, nationwide and worldwide.” *Id.* “A corporation that operates in many places can scarcely be deemed at home in all of them.” *Id.* Otherwise, “at home” would be synonymous with the “substantial, continuous, and systematic course of business” test that the Court rejected. *Id.* at 761-762 & n.20. Only in “exceptional” cases will a corporation be “at home” in a State other than its place of incorporation or principal place of business. *Id.* at 762 n.19.

B. Under *Daimler*, a Company Is Subject to General Jurisdiction Only in Its Place of Incorporation or Principal Place of Business Except in “Exceptional” Cases.

Following *Daimler*, the Ninth Circuit has applied the Supreme Court’s updated general jurisdiction analysis to prevent improper assertions of personal jurisdiction. In *Martinez v. Aero Caribbean*, the court held that a corporation organized and with its principal place of business in France was not subject to general jurisdiction in California even though it: (1) contracted to sell airplanes to a California corporation for hundreds of millions of dollars; (2) had contracts with eleven California component suppliers; (3) sent representatives to California to attend conferences, promote the corporation’s products, and meet with suppliers; and (4) advertised in trade publications distributed in California. 764 F.3d 1062, 1070 (9th Cir. 2014).

Other federal courts are in accord. In a case remarkably similar to this one, the Fifth Circuit affirmed last month that an Israel-based drug manufacturer was not subject to general jurisdiction in Louisiana where the plaintiffs alleged that an anti-nausea medication allegedly caused a birth defect. *Whitener v. Pliva, Inc.*, __ F. App’x __, 2015 WL

1570051, at *1-2 (5th Cir. Apr. 9, 2015) (per curiam). Similarly, other federal courts have held that attending an annual trade show in Chicago, using that show to collect e-mail addresses of Illinois residents for marketing purposes, targeting Illinois customers through a specific marketing package, and attracting Illinois residents to a Wisconsin ski resort “come[s] nowhere close to the *Goodyear/Daimler* standard for general jurisdiction. *Kipp v. Ski Enter. Corp. of Wis., Inc.*, __ F.3d __, 2015 WL 1692875, at *3 (7th Cir. Apr. 15, 2015) (*Daimler* “raised the bar” for general jurisdiction and requires “more than the ‘substantial, continuous, and systematic’ course of business” that was once thought to suffice).

The fact that a company even has branch offices and employees located in a particular state does not justify assertion of general jurisdiction. *Gucci Am., Inc. v. Weixing Li*, 768 F.3d 122, 135 (2d Cir. 2014) (holding inconsistent with due process to subject defendant global bank to general jurisdiction in New York notwithstanding that it had branch offices there); see also, e.g., *United States ex rel. Imco Gen. Constr., Inc. v. Ins. Co. of Pa.*, No. C14-0752RSL, 2014 WL 4364854, at *3 (W.D. Wa. Sept. 3, 2014) (insurance company not subject to general

jurisdiction in Washington even though it: (1) had been registered to do business there since 1909; (2) had 217 agents registered to do business in Washington, 79 of whom kept offices in Washington; (3) earned over \$53 million in premiums from Washington accounts in the last four years; and (4) had sued and been sued in the Western District of Washington within the last decade).

C. GSK is Not “At Home” in Montana for Purposes of General Personal Jurisdiction.

Applying the *Daimler* analysis to GSK is straightforward and establishes that GSK cannot be subject to general personal jurisdiction in Montana. GSK is a limited liability company (“LLC”) organized under the laws of the State of Delaware whose sole member is GSK Holdings. Ex. A, ¶2-3. GSK Holdings is a Delaware corporation with its headquarters and principal place of business in Delaware. *Id.*, ¶3. GSK’s principal U.S. operations and corporate offices are located in North Carolina and Pennsylvania. *Id.*, ¶4. Neither GSK nor GSK Holdings is incorporated in Montana, nor does either entity have its principal place of business in Montana. Therefore, GSK is not subject to general jurisdiction in Montana. *See Daimler*, 134 S.Ct. at 760.

In *Daimler*, the Supreme Court carved out one exception to its rule governing general jurisdiction for instances where a company’s “affiliations with the [forum] State are so ‘continuous and systematic’ as to render [it] essentially at home [there].” *Id.* at 761 & n.20.

Although GSK does certain, limited business in Montana, this is not an “exceptional” case in which GSK’s operations in the State support a finding that it is “at home” here for general jurisdiction purposes. *See id.* at 762 n.19. GSK’s Montana business operations account for only a tiny fraction of its nationwide footprint, much less its worldwide presence and activities. *See id.* at 762 n.20; *Martinez*, 764 F.3d at 1070 (the general jurisdiction test requires an appraisal of a company’s activities in their entirety).

GSK operates only one small-scale facility in Montana out of its 32 total facilities in the U.S. Ex. A, ¶¶13, 18. The Montana facility conducts no activities related to Zofran®. *Id.*, ¶18. Rather, the facility is part of GSK’s vaccines business, a separate division of the company from the pharmaceutical business, and lacking any connection to Zofran®. *Id.* GSK employs approximately 222 individuals in Montana, which is less than 1.3% of the more than 16,700 people employed by

GSK in the United States. *Id.*, ¶¶13, 19. None of GSK’s Montana employees, vendors, and agents has any involvement with or responsibilities related to Zofran®. *Id.*, ¶19. By comparison, in the first quarter of 2015, GSK employed 4,420 individuals in North Carolina—where its U.S. pharmaceutical operations and corporate offices are located—and 4,830 employees in Pennsylvania—where GSK maintains other significant operations and offices across seven different facilities. *Id.*, ¶20.

None of GSK’s management-level activities take place in Montana. *Id.*, ¶¶5-8. As noted, GSK has centralized pharmaceutical operations and corporate offices in two facilities in North Carolina and seven facilities in Pennsylvania. *Id.*, ¶4. As a member-managed limited liability company, all of GSK’s significant business decisions are made by its Board of Managers, none of whom are located in Montana. *Id.*, ¶¶2-3, 7-8. Its sole member, GlaxoSmithKline Holdings (Americas) Inc., (“GSK Holdings”), through its officers and directors, controls and approves all significant decisions regarding GSK Holdings’ business in Delaware. *Id.*, ¶7. Those officers and directors have offices in England,

Delaware and Philadelphia, and hold their board meetings in Delaware.
Id., ¶¶6-8.

Given GSK's miniscule presence in Montana compared to its nationwide and global operations, there is simply no basis for subjecting GSK to general jurisdiction in Montana. Simply put, this is an ordinary case of a company that operates in many places but "can scarcely be deemed at home in all of them." *Daimler*, 134 S.Ct. at 762 n.20. Subjecting GSK to general jurisdiction in Montana would violate due process. *Id.*

CONCLUSION

For the reasons stated above, GSK's motion to dismiss should be granted.

Dated: May 19, 2015

Respectfully submitted,

/s/ W. Scott Mitchell

HOLLAND & HART LLP

Counsel for Defendant

CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the requirements of Rule 7.1(d)(2). The lines in this document are double spaced, except for footnotes and quoted and indented material, and the document is proportionately spaced with Century Schoolbook font typeface consisting of 14 characters per inch. The total word count is 3,341 excluding caption and certificates of service and compliance. The undersigned relied on the word count of the word processing system used to prepare this document.

/s/ W. Scott Mitchell

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